Supreme Court, U.S.
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No.

In the Supreme Court of the United States

WILLIAM J. CATALONA, *ET AL.*, PETITIONERS

v.

WASHINGTON UNIVERSITY, RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Department of Health and Human Services regulations prohibit federally funded institutions from obtaining consent for medical research on human subjects by using "*any* exculpatory language through which the subject or the representative is made to waive or appear to waive *any* of the subject's legal rights," 45 C.F.R. § 46.116 (emphasis added), including (according to the Department's authoritative interpretation) the statement that "[b]y consenting to participate in this research, I give up *any property rights* I may have in bodily fluids or tissue samples obtained in the course of the research" (emphasis added). Exculpatory Language in Informed Consent, Office for Human Research Protections.

The question presented is whether these prohibitions bar contractual language requiring relinquishment of human subjects' ownership rights, and thus preempt state law to the extent it would otherwise work a forfeiture of those rights.

PARTIES TO THE PROCEEDINGS

Dr. William J. Catalona and his patients Antonio Castro, James D. Ellis, Luis Garcia, Mike Missios, Ivan Parron, Richard N. Ward, and Phillip Wiland were appellants in the court below. Washington University was the appellee in the court below. There are no other parties.

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INTRODUCTION

This case is about ownership of irreplaceable human cancer tissues provided to researchers according to the federal "Common Rule," a regulation so-called because it commonly applies to all federally funded research on human subjects. Petitioner Dr. William J. Catalona was Head of Urology at Respondent Washington University for more than a decade. When Dr. Catalona moved to another institution, thousands of patients who provided cancer tissues for his studies asked the University to send their tissues to Dr. Catalona. The University responded by suing Dr. Catalona to establish that it owned the tissues "pursuant to applicable federal and state regulations." Pet. App. 35a. After joining eight of Dr. Catalona's patients as defendants, the District Court held that the University owned the tissues with no strings attached under state and federal law. The Eighth Circuit disagreed that the patients relinquished all rights in their tissues, but agreed that the University ultimately owned them. In so doing, the Eighth Circuit improperly chose not to address the question whether any transfer of ownership was barred by the Common Rule, which precludes ownership transfers.

By refusing to recognize the Common Rule's preemptive effect, the Eighth Circuit's decision conflicts with the decisions of Maryland's highest court and another federal court, which hold that the provision of the Common Rule at issue here trumps state common law. Review is needed to settle this conflict, and to address the immense, immediate risk to millions of research participants across the country whose identifiable genetic information may now be consumed, published, used for ethically objectionable research, or simply sold to the highest bidder.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eighth Circuit is reported at 490 F.3d 667 and reprinted at Pet. App. 1a-18a. The opinion of the United States District Court for the Western District of Missouri (Limbaugh, D.J.) is reported at 437 F. Supp. 2d 985 and is reprinted at Pet. App. 21a-54a.

JURISDICTION

The court of appeals entered its judgment on June 20, 2007. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND REGULATORY PROVISIONS INVOLVED

The Supremacy Clause of the U.S. Constitution provides that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof * * * shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, § 2. The relevant federal regulation is reprinted at Pet. App. 58a-62a.

STATEMENT

1. From approximately 1976 to 2003, Petitioner Dr. William Catalona provided medical care and conducted research at Washington University in St. Louis, Missouri. Pet. App. 4a. Dr. Catalona is one of the preeminent urologists in the country, and while at Washington University he performed thousands of surgeries, including prostate cancer surgeries. *Ibid.* Dr. Catalona is also a leading researcher. In 1983, he spearheaded the creation of a "biorepository" for the collection and storage of biological research materials

relating to prostate cancer research and related areas of inquiry. *Ibid.* This dispute centers on ownership and other rights in the materials in that biorepository.

2. The District Court stated that "[t]here are approximately 3,500 prostate tissue samples in the * * * Biorepository * * * [and] approximately 100,000 serum samples."[1] Pet. App. 23a. The Eighth Circuit noted that Dr. Catalona "was instrumental in establishing the GU Biorepository for the collection and storage of biological research materials." Pet. App. 4a. Dr. Catalona established research protocols for the cancer research studies and appointed other members of the urology division to specific research projects. Tr. 1:47; App. 39.[2]

Among those whose tissue samples are housed in the biorepository are the eight patient-Petitioners in this case (the "research participants" or "Patients"). All eight research participants are patients on whom Dr. Catalona performed prostate cancer surgery.

The prostate tissue samples Dr. Catalona obtained from the research participants and others are "linked" samples—that is, the samples are matched via a computer database to the identity of the research participant. Tr.2:111-112; App. 111. The database contains demographic information linked to each participant, including specific medical informa-

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[1] For ease of reference, this application will refer to all of the samples provided to Dr. Catalona as "tissue samples."

[2] "App." refers to the appendix to Petitioner's brief in the court below; "Tr." refers to the transcript of the three-day evidentiary hearing preceding the Court's summary judgment decision; and "Add." refers to the addendum to Petitioner's brief in the Court below.

tion such as prostate-specific antigen ("PSA") levels, disease diagnosis, past history of prostate cancer, and clinical follow-up data. Tr. 2:112-113; App. 111-112. The database also lists the identity of the treating physician for each research participant.

Linking the samples to the identity of their owner is important because cancer has a significant genetic component. If it were determined, for example, that a certain set of genetic variants predisposed an individual to cancer, it would obviously be important to inform the person from whom the tissue came that he was predisposed to cancer. But it would also be important to inform the relatives of that individual, when appropriate, because they too would be likely to have the same genetic predisposition. Tr. 2:124-126; App. 114-115.

Research participants could be harmed by the release of such information. As the University's own genetics brochure states, "*[i]f this information were to become known outside of the research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or be terminated from your current employment.*" Add. 35 (emphasis added). The information, once known, could also cause public embarrassment. See Alan F. Westin, Institute of Medicine Privacy & Research Studies, at 8 (Sept. 11-18, 2007) (national public survey finding embarrassment among concerns if personally-identified health information were disclosed) (on file with Study Director at Institute of Medicine).

3. Washington University is a federally approved and regulated institution with respect to the human-subjects research based in the biorepository. Because

Washington University receives federal funds, it must comply with regulations issued by the Department of Health and Human Services and 16 other federal departments and agencies that govern the conduct of human-subjects research. See 56 Fed. Reg. 28,003 (June 18, 1991) (codified at 45 C.F.R. pt. 46). Because of their applicability across the agencies, these regulations collectively are known as the Common Rule. See *id.* (providing the "Text of the Common Rule").

Among other things, the Common Rule protects participants by placing strict limits on what a research institution may seek consent to do:

> *No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights*, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. § 46.116 (emphasis added). Interpreting this regulation, the Office for Human Research Protections ("OHRP"), the enforcement arm of the Department of Health and Human Services, has issued authoritative guidance barring waivers of the patient's property rights in tissue samples provided for research. *See* Exculpatory Language in Informed Consent, Ofc. for Human Research Prot., *available at* http:// www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm (forbidding statement that "[b]y consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research").

Moreover, to constitute informed consent under the Common Rule, a consent document must contain certain provisions, including "[a] statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." 45 C.F.R. § 46.116(a)(8). Where "appropriate" the consent form must also state "[t]he consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject." *Id.* at § 46.116(b)(4).

Pursuant to the Common Rule, research participants were presented with consent forms and a brochure drafted by Washington University. Pet. App. 5a-6a. The forms provided that their tissue samples would be used for prostate and bladder cancer research and that "[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Pet. App. 6a. The forms did not state that Washington University (or Dr. Catalona) would own the tissue samples, but instead made clear—in a section entitled **"What if you change your mind?"**—that the patients retained significant ownership rights in their tissues, including the right to demand that their samples be destroyed upon their request. Pet. App. 27a (emphasis in forms and District Court opinion).

4. In early 2003, Dr. Catalona left Washington University to become a professor and director of the Clinical Prostate Cancer Program at Northwestern University in Chicago, Illinois. Pet. App. 7a. In February of that year, Dr. Catalona sent a form letter to his patients, the families of his patients, and all oth-

ers who participated in his research protocols at Washington University. The letter asked if the recipient would consent to having his tissue transferred from Washington University to Northwestern University. Pet. App. 7a-8a. Dr. Catalona also published his request in the medical newsletter *Quest*. Pet. App. 33a. The Petitioner-research participants, along with more than 6,000 other research participants, requested that the University withdraw their samples from research there and transfer the samples to Dr. Catalona. Pet. App. 8a.

The University refused to honor these requests and filed suit in federal District Court under state and federal law. Specifically, the University, which alleged jurisdiction based on diversity and federal questions, "argued that the [research participants] made voluntary donations . . , and once these 'gifts' were delivered to [the University], [the University] became the sole owner with control as to use and storage (pursuant to federal and state regulations)." Pet. App. 35a. Dr. Catalona and the Patients countered that, among other things, the Common Rule prohibited using "exculpatory language" in informed consent forms, including language transferring ownership of tissues, and thus "*negates* the gifts." *Id.* at 44a (emphasis added).

5. The District Court sided with the University, holding that the prohibition on exculpatory language merely barred the University from inducing patients to waive the University's negligence. Pet. App. 45a. The Court rejected OHRP's interpretation of the prohibition, which also bars transfer of ownership rights, on the ground that OHRP guidance was non-binding because it was not formally promulgated. *Ibid.* Declining to find federal preemption, the District Court

concluded that the Patients made a gift of their tissues to the University under Missouri law.

On appeal, both the Patients and Dr. Catalona, while relying primarily on state-law arguments, also pressed the federal question. The Patients explained that the Common Rule was "governing law," Pat. Open. Br. at 32, and its "*prohibition on exculpatory language bars waiver of the [research participants'] ownership rights in the samples provided for research*," Pat. Reply at 20 (emphasis added). Dr. Catalona, in his statement of issues, identified as one of the questions to be decided "*whether the exculpatory language in the patient consent agreements is invalid as a matter of law because it is forbidden by federal regulations.*" Statement of Issues at 2 (emphasis added). And he argued, among other things, that "the Common Rule establishes a minimum set of rights to be reserved to the Patients." Reply Br. at 12.

The Eighth Circuit refused to address the preemptive effect of the Common Rule, however, affirming the District Court strictly under Missouri's law of gifts. Pet. App. 17a. The Eighth Circuit issued its decision on June 20, 2007. This petition followed.[3]

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[3] The decisions below have prompted extensive coverage in leading national scientific and medical journals. See Jocelyn Kaiser, *Issues with Tissues*, 316 Science 1829 (June 29, 2007); Jocelyn Kaiser, *Biomedical Research: Court Decides Tissue Samples Belong to University, Not Patients*, 312 Science 346 (Apr. 21, 2006); Hakimian, R. & Korn, D., *Ownership and Use of Tissue Specimens in Research*, 293 Journal of the American Medical Association 1325 (Mar. 16, 2005); Charo, R.A., *Body of Research: Ownership and Use of Human Tissue*, 355 New England Journal of Medicine 1517 (Oct. 12, 2006); Goldman, Michael A., *Calamity Gene*, 445 Nature 819 (2007); Andrews, Lori.

REASONS FOR GRANTING THE PETITION

This Court's review is warranted because the ownership of millions of tissue samples transferred under the Common Rule hang in the balance—and with those samples, the irreplaceable, personally identifiable genetic information of millions of individuals, such as the eight patient-petitioners. This is a quintessential issue of national importance. See Sup. Ct. R. 10(a). Moreover, review is warranted because the decision below—ignoring the Common Rule's plain prohibition on the transfer of property rights, and thus rejecting its preemptive effect on state property law principles—is in conflict with decisions of Maryland's highest court and another federal court, which hold that the Common Rule's informed consent provision does in fact preempt state common law.

I. The Decision Below Has Profound, Nationwide Implications Because Of The Sweep Of The Common Rule.

By ignoring the text of the Common Rule and its authoritative interpretation, the Eighth Circuit has placed at risk the genetic privacy, and the availability of future gene-based health care, for millions of par-

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Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona, 34 J.L. Med. & Eth. 398 (2006).

They have also prompted in-depth coverage and commentary in national papers. See Cheryl Wittenauer, *Court: University Owns Research Samples*, USA Today, June 22, 2007, available at http:// www.usatoday.com/news/health/2007-06-22-161080136_x.htm; Crichton, Michael, *Body Snatchers*, Wall Street Journal, Dec. 15, 2006, at A20; Rebecca Skloot, *Taking the Least of You*, New York Times Magazine, Apr. 16, 2006, *available at* 2006 WLNR 6371120.

ticipants in federally sponsored trials "spread across hundreds of sites" throughout the country. See United States General Accounting Office, *Human Subjects Research: HHS Takes Steps To Strengthen Precautions, But Concerns Remain* 2 (May 2001) ("GAO Report"). A key reason for this risk is that genetic research is a booming business, and (as shown in this very case) institutions such as Washington University do not hesitate to use research participants' tissues for profit. Accordingly, this Court's review is urgently needed to ensure the proper interpretation of the Common Rule, which "deals with the rights, liberties, and personal freedoms of human beings, and is in an entirely different category from state * * * laws regulating the labels on cans." *Hines* v. *Davidowitz*, 312 U.S. 52, 68 (1941).

1. Although tissue collection began in earnest relatively recently (in part at Dr. Catalona's initiative), the number of tissues stored in the United States is already staggering. A "conservative" estimate from an inventory of national tissue collections taken more than *seven years ago* "is that more than 307 million tissue specimens from more than 178 million cases are stored in the United States, accumulating at a rate of 20 million per year." Elisa Eiseman & Susan B. Haga, *Handbook of Human Tissue Sources* xvii (1999) (RAND Corp.). Tissue banks established specifically for research account for 2.3 million specimens. *Ibid.* And experts believe that the largest financial supporter of such repositories is the National Institutes of Health, suggesting that most such research is governed by the Common Rule. *See id.* Though exact numbers are unavailable, moreover, the number of tissues subject to the Common Rule "has likely increased as federal spending for medical

and health research has doubled in recent years." GAO Report at 2.

This massing of tissues no doubt reflects not only the promise of genetic research, but also the prospect of financial profit. Tissue research is lucrative, a fact well summed up by David Korn, the Vice President of the Association of American Medical Colleges, an *amicus* in the court below: "Sure consent feels nice. Letting people decide what's going to happen with their tissue seems like the right thing to do. But consent diminishes the value of tissues." Rebecca Skloot, *Taking the Least of You*, New York Times Magazine, Apr. 16, 2006, *available at* 2006 WLNR 6371120. And this "value" is not merely informational.

In this very case, for example, the University's business development director wrote to a vice chancellor: "Bill Catalona wants to send nearly 2,000 documented samples to Hybertech for free. Just from a cost recovery scenario, this should be worth nearly $100,000 to the University. * * * It is my opinion this is an unacceptable proposal." App. 157:33.

Of course, the problem here is not the profit motive *per se*, but the strong potential for conflicts of interest that compromise researchers' commitment to protecting patients. The General Accounting Office describes this danger:

> [i]n today's environment, financial relationships sometimes exist between investigators, institutions, and industry sponsors. These relationships have the potential to inappropriately influence the professional judgment and independence of those responsibility for the protection of human subjects. In particular, they can affect the study's recruitment, enrollment, conduct, and analysis of

> results in ways that would financially benefit the investigator or institution.

GAO Report at 8. Indeed, even research *advocacy* can be a profit center subject to the forces of potential ethical compromise. Serious questions have long been raised, for example, about whether the American Cancer Society (also an *amicus* below) should remain a non-profit institution. See, *e.g.*, Samuel Epstein, *American Cancer Society: The World's Wealthiest "Non-Profit" Institution*, 29 Int'l J. Health Serv's 565, 566 (1999) (arguing that the Society is "more interested in accumulating wealth than saving lives") (quotation omitted).

2. The importance of enforcing existing federal protections is further underscored by science's ever-increasing mastery of genetics. To be sure, "[t]he modern story of human subjects protections begins with the Nuremberg Code, developed * * * as standards by which to judge the human experimentation conducted by the Nazis." Office of Human Research Protections, Institutional Review Board Guidebook, available at: www.hhs.gov/ohrp/irb/irb_introduction. And the capstone of that Code is the declaration that "the voluntary consent of the human subject is absolutely essential," including the freedom to "withdraw at any time." *Ibid.* But the importance of these rights expands geometrically when, as is the case today, the "human subject" participates via his personally identifiable DNA, which may well hold the key, not only to his own disease risk, but also that of his *descendants*. It is truly a Brave New World.

Nor are these risks eliminated by the Eighth Circuit's holding that, if participants change their minds, they are entitled to order their tissues not to

be used for further research or destroyed. Pet. App. 14a, 15a. It may be impossible, as a practical matter, for participants to track down their tissues once sold or transferred across the country. Moreover, under the Eighth Circuit's decision, there remains the risk that research results will be published—and once in the public domain they will be lost forever. This could be devastating because, according to Washington University's own consent forms, "[i]f this information were to become known outside of th[is] research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or terminated from your current employment." Add. 35. In national public survey taken several weeks ago, The Institute of Medicine of the National Academies found that such fears are shared by much of the U.S. population. Westin, *supra*, at 8.

And there are still other risks. According to Professor Lori Andrews, if the Eighth Circuit's decision stands, "in contravention of a patient's wishes, the tissue could be used in research to create a human clone. It could be used for a type of research that violated a patient's religious beliefs, such as embryonic stem cell research." Lori Andrews, *Who Owns Your Body? A Patient's Perspective on* Washington Univ. v. Catalona, 34 J.L. Med. & Ethics 398, 405 (2006). "In 2004," Professor Andrews notes, "the Native American Havasupai tribe of Arizona filed a $50 million lawsuit claiming 400 samples given to local universities for the purpose of diabetes research were used for studies on inbreeding, schizophrenia and ancient human population migrations to North America." *Ibid.* According to Professor Andrews, "tribe members asserted they were stigmatized by the schizo-

phrenia and inbreeding research and would not have consented to the origins studies because they directly conflicted with the tribe's religious beliefs." *Ibid.* The case is on appeal. See Lindsey Collom, *Judge Tosses Tribe's Case on Technicality; Havasupais To Appeal Suit Over Blood Samples*, The Arizona Republic, May 4, 2007, at 1.

In short, the Eighth Circuit's decision in this case is of critical national importance because it establishes that the Common Rule does not protect research participants' ownership of their *personally identifiable genetic material.* Not only is this irreplaceable and financially valuable, it may well contain the participants' disease propensities and that of their children, and its use by their institutional "owners" may violate the ethical convictions of their true owners.

II. The Decision Below Is Incorrect And Conflicts With The Highest Court Of The State Of Maryland, And Another Federal Court, On The Preemptive Effect Of The Common Rule.

In addition to trampling on research participants' rights in their personally identifiable genetic information, the Court below also created a split of court authority. Specifically, by refusing to address petitioners' arguments that the Common Rule's informed consent provision prohibits the transfers of property rights in tissues, the Court effectively ruled that the provision is without preemptive effect. That is not what the highest court of the State of Maryland and the U.S. District Court for the Southern District of New York have said, and this Court should take this case to resolve this conflict.

1. "It is a familiar and well-established principle that the Supremacy Clause, U.S. Const. art. VI, cl. 2, invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County* v. *Automated Med. Labs, Inc.*, 471 U.S. 707, 712-713 (1985) (quoting *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.)). Congress may preempt state law expressly or by establishing a regime of pervasive federal regulation that occupies a particular field. See *English* v. *General Elec. Co.*, 496 U.S. 72, 78 (1990). In addition, federal law preempts state law where there is a conflict between the two, either because it is impossible to comply with both federal and state law, *ibid.*, or because the requirements of state law "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines*, 312 U.S. at 67. Regulations (not just statutes) can have such preemptive effect, *Hillsborough County*, 471 U.S. at 713, and may do so as against state common-law rules as well as positive enactments, see, *e.g.*, *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 884-885 (2000).

Applying these principles, the Maryland Court of Appeals holds that the Common Rule's informed consent provision preempts Maryland common law. The plaintiffs in *Grimes* v. *Kennedy Krieger Institute*, 782 A.2d 807 (Md. 2001), brought negligence actions for injuries allegedly sustained by their children while participating in a research study. *Id.* at 818. The question at issue was whether a researcher-participant relationship could constitute a "special relationship" giving rise to duties that, in turn, could support negligence actions. *Id.* at 819.

The Court held that research-participant relationships could constitute such "special relationships,"

and that the Common Rule can create such a relationship. According to the court, contrary to 45 C.F.R. § 46.116—the same provision of the Common Rule at issue in this case—the children at issue were involved in the research without their parents' fully informed consent. 782 A.2d at 848. Further, the Court considered whether this duty of informed consent under federal law "translate[d] into a duty of care arising out of the unique relationship that is researcher-subject, as opposed to doctor patient," and "answer[ed] that question in the affirmative." *Id.* at 849.

Under *Grimes*, then, the Common Rule's informed consent requirements can *raise* a researcher's duty of care under state law, which otherwise would be an obstacle to the achievement of federal objectives. That is, the Common Rule's informed consent requirements preempt state common law.

2. The U.S. District Court for the Southern District of New York has reached the same conclusion. In *Karemer-Katz* v. *United States Public Health Service*, 872 F. Supp. 1235 (S.D.N.Y. 1994), the plaintiff claimed that state common law afforded her the right to continue in a federally sponsored new-drug investigation terminated by researchers. The court disagreed, noting that under 45 C.F.R. § 116, a research participant must be informed of "[a]nticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent." 872 F. Supp. at 1240. This rule established that, "provided that advance notice is given," a participant may be terminated—regardless of state law.

The court further explained that, *"[a]ny interpretation of state law destroying this option by treating termination as improper abandonment of the patient would 'undercut' the objectives of federal law and hence be preempted." Ibid.* (emphasis added). It concluded: "State law interpretations which cause interference with policies implicated by the structure of federal statutes are barred." *Ibid.* (quotation omitted).

3. The very same provision of the Common Rule is at issue here, and likewise preempts state law. Petitioners presented this issue to the Eighth Circuit, which simply failed to address it. This was effectively a finding of *non*-preemption, and it creates a split of authority with *Grimes* and *Karemer-Katz*.

As noted, Washington University is a federally approved and regulated institution with respect to the human subjects-research at issue in this case. Among other things, the Common Rule forbids any consent document containing *"any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights*, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence." 45 C.F.R. § 46.116 (emphasis added).

The Office for Human Research Protections (the enforcement arm of the Department) has given authoritative guidance on the meaning of § 46.116. See Exculpatory Language in Informed Consent, Office for Human Research Protections, *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm. The guidance document details various provisions that are impermissible under § 46.116, including the statement that "[b]y consenting to participate

in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research." *Ibid.* By contrast, acceptable language includes: "[b]y consenting to participate, you authorize the *use* of *your* bodily fluids and tissue samples for the research described above." *Ibid.* (emphasis added).

Here, the Eighth Circuit nevertheless held that the language used in the Washington University consent forms had precisely the effect proscribed by the federal regulation—transferring ownership of the samples to the University. Pet. App. 17a. And this is true apart from the forms' specific "waiver" clause, on which the Eighth Circuit did not rely. Pet. App. 15a n.7. As the court reasoned, the consent forms "characterized the [Patients'] participation as a 'donation'," and "[t]he brochure * * * characterized the [Patients'] donations as a 'free and generous gift.'" Pet. App. 12a, 13a.

Petitioners believe that reading is incorrect as a matter of state contract law, but the more important point, for present purposes, is that the consent forms, if so interpreted, violate the Common Rule and its interpretation by the Department of Health and Human Services. That interpretation allows patients to grant researchers "use" of their tissues but *prevents* researchers from obtaining property rights—including ownership rights—in those tissues. 45 C.F.R. § 46.116; Exculpatory Language in Informed Consent, Office for Human Research Protections.

Most importantly, under the reasoning of *Grimes* and *Karemer-Katz*, the Common Rule preempts Missouri law to the extent it would require a result at variance with the Rule. As construed by the Eighth

Circuit, Missouri law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines*, 312 U.S. at 67) as interpreted by the Department of Health and Human Services in the Common Rule and its accompanying guidance documents. As shown by those authorities, the federal purpose and objective was to prevent research participants from having to give up "any of [their] legal rights," 45 C.F.R. § 46.116, including "any property rights [they] may have in bodily fluids or tissue samples," Exculpatory Language in Informed Consent, Office for Human Research Protections. In other words, the federal government intends that participants cannot relinquish ownership rights in their tissues as a condition of participating in federally funded research. Yet that is precisely what the District Court and the Eighth Circuit held occurred here under Missouri law. But if that is true, that result is preempted by the Common Rule as a matter of federal supremacy.

Hillsborough confirms this conclusion. The question in *Hillsborough* was whether Food and Drug Administration ("FDA") regulations preempted a county's rules setting an even higher standard for blood plasma donor testing and recordkeeping. 471 U.S. at 714-715. This Court held that the FDA, in interpreting its statutory mandate, did not preempt state law, because the FDA never suggested that its goals (to protect the blood and plasma supply) were in conflict with those of the County (also to protect the blood and plasma supply).

Preemption is appropriate here because the situation is precisely the opposite. First, the Common Rule suggests that it *is* intended to supersede state laws—unless they set a higher standard for disclo-

sure than the Rule. See, *e.g.*, 45 C.F.R. § 46.116(e) ("The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws *which require additional information to be disclosed in order for informed consent to be legally effective.*") (emphasis added). Second, the Rule and its accompanying guidance show that the Department's intent was to forbid the relinquishment of proprietary rights in tissues. Thus, whereas in *Hillsborough* the agency's stated goals existed in concert with the relevant local ordinance, here HHS's goals are at cross-purposes with Missouri law.

In sum, the conflict is crystal clear: whereas the Common Rule and its authoritative interpretation emphasize the need to preserve patients' ownership rights in their irreplaceable, personally identifiable genetic material, Missouri's law of gifts (as construed by the court below) ignores that need and mandates that patients' property rights will not be preserved as deemed safest by HHS. This is thus a classic case of purpose-conflict preemption, which the Maryland Court of Appeals and the Southern District of New York would have recognized. This Court should resolve the conflict among the lower courts created by the Eighth Circuit's decision.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 2007

APPENDIX

APPENDIX A

United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 06-2286

Washington University, *
*
Appellee, *
*
v. *
*
William J. Catalona, M.D., *
*
Appellant. *

No. 06-2301

Appeals from the United States District Court for the Eastern District of Missouri

Washington University, *
*
Appellee, *
*
v. *
*
Richard N. Ward; Thomas *
A. McGurk, Jr.; Luis *
Garcia; Antonio Castro; *
Philip Wilard; *
Ivan Parron; James D. *

Ellis, Mike Missios, *

*

Appellants. *

Us Too International; *
People's Medical Society, *
*
Amici on Behalf of *
Appellants, *
*
American Cancer Society; *
Cornell University; *
Duke University; Emory *
University; The George *
Washington University; *
Johns Hopkins University; *
Mayo Clinic; The Board of *
Trustees of the Leland *
Stanford Junior University; *
The University of Michigan; *
University of Minnesota; *
The University of *
Pittsburgh; The University *
of Rochester; American *
Council on Education; *
Association of American *
Medical Colleges; *
Association of American *
Universities, *
*
Amici on Behalf of *
Appellee. *

Submitted: December 13, 2006
Filed: June 20, 2007

Before WOLLMAN, RILEY, and SHEPHERD, Circuit Judges.

RILEY, Circuit Judge.

We are asked to determine the ownership of biological materials contributed by individuals for the purpose of genetic cancer research and currently housed on the campus of Washington University (WU). WU brought a declaratory judgment action against Dr. William Catalona (Dr. Catalona), a former WU medical school faculty member, seeking to establish WU's ownership of the research biological materials. Dr. Catalona counterclaimed, seeking a declaration the contributing individuals could direct the transfer of their biological materials to him. Dr. Catalona also moved for an order prohibiting WU from utilizing, disseminating, transferring, or destroying the biological materials at issue. The district court[1] concluded WU owns the biological materials and neither Dr. Catalona nor any contributing individual has any ownership or proprietary interest in the disputed biological materials. These appeals followed. We affirm.

1. BACKGROUND

WU, a prominent private research university located in St. Louis, Missouri, houses its own medical school, including a Division of Urologic Surgery (Division). Within the Division, WU physicians treat patients, teach students and residents, and conduct

[1] The Honorable Stephen N. Limbaugh, United States District Judge for the Eastern District of Missouri.

medical research on urologic diseases such as prostate cancer. Dr. Catalona, a highly respected urologist and urologic surgeon and researcher, was employed by WU from 1976 to 2003, and he served as Division Chief from 1984 to 1998. During Dr. Catalona's tenure at WU, he performed thousands of surgeries, many involving prostate cancer. As a leading medical researcher for WU, one of Dr. Catalona's principal areas of research was the genetic basis of prostate cancer. In 1983, Dr. Catalona began collecting samples of biological materials, such as blood and tissue removed during surgery, to be used later for prostate cancer research. Dr. Catalona encouraged his colleagues to do the same.

Dr. Catalona was instrumental in establishing the GU[2] Biorepository (Biorepository), the world's largest storage facility for biological samples collected by Dr. Catalona and other WU physicians for prostate cancer research. The Biorepository is housed in one or more buildings owned by WU. WU provides the majority of funding necessary to support the maintenance and operation of the Biorepository. Additional funding is provided by public and private grants payable to and administered by WU as the "grantee." While employed by WU, Dr. Catalona raised several million dollars in outside funding for the Biorepository. Other WU employees, including Dr. Catalona's successor as Division Chief, also have raised a substantial amount of funds.

During the relevant time period, Dr. Catalona and other Division physicians performed many genetic cancer research studies, with each study naming a particular WU physician as the "principal

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[2] GU is an abbreviation for genito-urinary.

investigator, a term designating the person "in charge of conducting the research protocol." Regardless of the physician designated as principal investigator on a particular research study, the named principal investigator generally collaborated with several other individuals in the research studies.

In order to conduct these studies, individuals were invited to participate in genetic research. Individuals who chose to donate excised prostate tissue or a blood sample to medical research and to become a research participant

(RP) were required to complete an informed consent form.[3] Although the language of the consent forms differs, depending upon the nature of the particular study or the study's principal investigator, generally all of the forms contain similar provisions, such as the WU Medical Center or WU School of Medicine logo, the principal investigator, the purpose of the research, and the nature of the RP's participation.

The consent forms often used the term "donation" to describe the biological sample's transfer from the RP to a WU physician or medical technician. The forms also noted biological samples "may be used for research with our collaborators at [WU], other institutions, or companies." The consent forms typically provided that by participating in the study, the RP "agree[s] to waive any claim [he] might have to the body tissues that [he] donate[s]" and also "waive[s] the right to any new material or process

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[3] Fifteen versions of the consent forms, used for six different research studies, were admitted into evidence before the district court.

developed through research involving [his] tissues". RPs also were informed by the consent forms, "Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Some consent forms indicated RPs could request destruction of their biological materials if they changed their minds about participating in the study, but noted it would not be possible to destroy or recall any research results already obtained. Other consent forms made no mention about an RP's right to request destruction of materials donated to research.[4]

In addition to the consent form, RPs received a genetic research information brochure (brochure) to review and sign. The brochure provided RPs' tissue samples (1) will be used by "[WU] Medical Center researchers," (2) "maybe shared with other authorized researchers doing research in similar fields at [WU] and other research centers," and (3) "may be used for studies currently in progress or studies conducted 10 or 20 years from now." Similar to the consent forms, the brochure used the term "donation to describe the RP's participation, noting, "By agreeing to participate, you are making a free and generous gift of your tissue to research that may benefit society." The brochure advised RPs, "You will receive no monetary payment for your tissue nor can you claim ownership rights to any medical or scientific product that results from research with your tissue." The brochure also informed RPs of their right to have their biological materials destroyed upon request should they change their minds about participating in the research study.

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[4] Forms signed by seven of the eight defendant-patients fall within this category.

At the time of the district court's permanent injunction hearing in this case, more than 30,000 RPs were enrolled in WU prostate cancer research studies. About 2,500 to 3,000 RPs had been patients of Dr. Catalona. The Biorepository contains: (1) approximately 3,500 prostate tissue samples taken from patients of Dr. Catalona and other WU physicians within the Division; (2) about 100,000 blood or serum samples donated by over 28,000 men, 75% of whom were not patients of any WU physician, but rather were volunteers recruited through the media; and (3) DNA samples provided by approximately 4,400 men, which included patients of different WU physicians and relatives of those patients.

Over the years, other research institutions requested and received biological samples from the Biorepository to conduct genetic cancer research projects either in partnership with or independent of WU. While at WU, Dr. Catalona repeatedly transferred Biorepository materials to other research institutions pursuant to material transfer agreements (MTAs). The MTAs typically were signed by an authorized WU official as well as a providing investigator. Several MTAs personally signed by Dr. Catalona, as the principal or providing investigator, acknowledge WU as the owner of the biological samples.

In early 2003, Dr. Catalona accepted a faculty position at Northwestern University in Chicago, Illinois. Given his plan to continue genetic research in the area of prostate cancer, Dr. Catalona sent a letter in February 2003 to his patients, their relatives, and other individuals who had served as RPs informing them of his departure from WU and

requesting transfer of biological materials. Attached to the letter was a "Medical Consent & Authorization" form (release form). In addition, both the letter and release form were printed in a newsletter from the Urological Research Foundation, for which Dr. Catalona served as the medical director. Dr. Catalona estimated between 50,000 and 60,000 individuals received the letter and release form. Although Dr. Catalona was still a WU employee at the time he sent the letter and release form, Dr. Catalona was no longer the principal investigator on any of the research protocols involving biological samples he sought to have transferred to Northwestern University. Neither the letter nor the release form were approved by any WU administrators or WU's institutional review board. The letter discussed, among other things, Dr. Catalona's availability for treatment, his continuation of prostate cancer research, and his need for the tissue and blood samples "contributed to [him] over the years." In connection with Dr. Catalona's stated necessity, the letter requested the recipient sign and return to Dr. Catalona the attached release form, which set forth the following language:

> I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects.

Approximately 6,000 RPs returned completed release forms to Dr. Catalona.

A. Procedural Background

On August 4, 2003, WU filed a declaratory judgment action against Dr. Catalona, seeking to establish WU's ownership of the Biorepository and the biological materials contained therein. Dr. Catalona counterclaimed and sought a declaration that the RPs have the right to direct the transfer of their biological samples to him. In January 2004, WU moved for summary judgment. On June 8, 2004, after filing several extensions to respond to WU's summary judgment motion, Dr. Catalona moved for an order prohibiting WU from utilizing, disseminating, transferring, or destroying the genetic material at issue. The following day-and before WU could respond-the district court temporarily granted the motion. WU then moved to set aside the district court's order, arguing Dr. Catalona was truly seeking a preliminary injunction. The district court agreed, withdrew its June 9, 2004, order, converted Dr. Catalona's motion to a motion for a preliminary injunction, and set the motion for hearing.

On February 11, 2005, in an effort to resolve continuing disputes between the parties on the priority of the pending motions, the district court, sua sponte, ordered a permanent injunction hearing for April 11, 2005. On February 22, 2005, eight of Dr. Catalona's patients who served as RPs,[5] sought to intervene in support of Dr. Catalona. Upon finding the eight men were necessary parties to the litigation, the district court ordered they be joined as defendants.

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[5] The men included Richard N. Ward; Thomas A. McGurk, Jr.; Luis Garcia; Antonio Castro; Phillip Wilard; Ivan Parron; James D. Ellis; and Michael Missios.

Following a three-day hearing on the permanent injunction, the district court found (1) WU was the owner of the biological samples housed in the Biorepository, (2) neither Dr. Catalona nor any RP in connection with any research protocols conducted under the auspices of WU had any ownership or proprietary interest in the biological samples in question, and (3) none of the release forms authored by Dr. Catalona and signed by any RP were effective to transfer ownership or possession of the biological samples to Dr. Catalona or to any other research facility or individual. Wash. Univ. v. Catalona, 437 F. Supp. 2d 9855 1002 (E.D. Mo. 2006). Therefore, the district court granted WU's motion for summary judgment and denied Dr. Catalona's motion to enjoin WU's use of the biological samples. This appeal followed.

II. DISCUSSION

A. Standards of Review

Because the district court's finding that WU owns the biological samples resolved all issues in the case, we have jurisdiction under 28 U.S.C. § 1291 to review the defendants' appeal from a final decision of the district court. We review de novo the district court's grant of summary judgment. See Burlington N. & Santa Fe Ry. Co. v. State Tax Comm'n, 188 F.3d 1039, 1041 (8th Cir. 1999). We may affirm a grant of summary judgment on any ground supported by the record. See P & O Nedlloyd, Ltd. v. Sanderson Farms, Inc., 462 F.3d 1015, 1018 (8th Cir. 2006). We review the district court's denial of injunctive relief for an abuse of discretion. See Int'l Ass'n of Machinists & Aerospace Workers, Dist. Lodge No. 19 v. Soo Line R. Co., 850 F.2d 368,374 (8th Cir. 1988) (en banc). An

abuse of discretion occurs if the district court bases its decision on an erroneous application of the law or a clearly erroneous factual finding. See Taylor Corp. v. Four Seasons Greetings, LLC, 403 F.3d 958, 967 (8th Cir. 2005).

B. Ownership of the Biological Materials

We now turn our attention to the pivotal inquiry in this dispute: whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party. Under the facts of this case, the answer is no.

In deeming WU the owner of the biological samples, the district court found all RPs donated their biological materials to WU as *inter vivos* gifts.[6] Wash. Univ., 437 F. Supp. 2d at 999. In addressing this issue, we look to the substantive law of Missouri, which defines an *inter vivos* gift as "a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction." Pilkington v. Wheat, 51 S.W.2d 425 44 (Mo. 1932); see, e.g. Wills v. Whitlock, 139 S.W.3d 6435 653 (Mo. Ct. App. 2004). As the party claiming the existence of an *inter vivos* gift, WU bears the burden to prove by clear and convincing evidence there was (1) present intent of the donor to

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[6] Whether the RPs made inter vivos gifts is a state law question of fact. See Estate of Thompson v. Hicks, 148 S.W.3d 32, 36 (Mo. Ct. App. 2004). We review de novo the district court's interpretation of state law. See Protective Life Ins. Co. v. Jim Orr & Assoc., Inc., 384 F.3d 9495 950 (8th Cir. 2004).

make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee, whose ownership takes effect immediately and absolutely. See Clippard v. Pfefferkorn, 168 S.W3d 6165 618 (Mo. Ct. App. 2005). The RPs unquestionably delivered their biological materials to WU at the time of their donation; thus, we focus our inquiry on the first and third elements.

With regard to the first element, we assess the donor's intent by examining whether a gift was intended at the time of the transaction. No specific language is required to reflect the donor's present intent to make a gift; in fact, the circumstances surrounding the contribution may create an inference the donor intended to make a valid *inter vivos* gift. See Duvall v. Henke, 749 S.W.2d 714, 716 (Mo. Ct. App. 1988). However, the donor must intend "to part with his right in and dominion over the property immediately and irrevocably." Ridenour v. Duncan, 246 S.W.2d 765, 769 (Mo. 1952). Here, the circumstances surrounding the RPs' decisions to participate in genetic cancer research demonstrate the status of the RPs as donors and their intent to make gifts of their biological materials to WU's medical research activities. Before participating in WU's research activities, each RP was required to read and sign the consent form, which bore WU's logo and characterized the RP's participation as a "donation" of bodily tissues or blood. The consent form emphasized the voluntariness of the RP's participation and discussed the RP's right to decline participation in the study or to withdraw consent at any time. Although some RPs were Dr. Catalona's patients, many other RPs were patients of different WU doctors and participated in research studies

designating someone other than Dr. Catalona as the principal investigator. Even the consent forms designating Dr. Catalona as the study's principal investigator invited RPs "to participate in a research study conducted by Dr. William J. Catalona and/or *colleagues*" (emphasis added). The consent forms also advised RPs their biological samples "may be used for research with our collaborators at [WU], other institutions, or companies."

Our conclusion the RPs intended to make gifts of their biological samples at the time of their donation is bolstered further by the language of the brochure, which characterized the RPs' donations as "a free and generous gift of [biological materials] to research that may benefit society." The brochure's acknowledgment that donated materials may be shared with non-WU researchers, without any further authorization needed from the RPs, informed the RPs they would relinquish or abandon the right to designate the particular destination of their biological materials upon agreeing to participate in a medical research study. Such language, considered together with the consent form, cannot reasonably be characterized as reflecting the RPs' intention either to entrust their samples solely to Dr. Catalona or to transfer the samples in some legal form other than a gift.

With regard to the third element acceptance of the gift by the donee-the defendants contend the RPs retained significant rights in the donated materials, and thus the transfer of materials to WU could not have been absolute. We disagree. WU accepted and retained absolute possession of the biological materials immediately upon donation. Although Missouri law generally prohibits a donor from revoking a completed *inter vivos* gift once the gift is

delivered to and accepted by the donee, an *inter vivos* gift nevertheless may be subject to a condition allowing the donor to exercise a particular revocation right in the future. See Clippard, 168 S.W.3d at 619; see, e.g. Franklin v. Moss, 101 S.W.2d 7115 714 (Mo. 1937). The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid *inter vivos* gift. See 14 C.J.S. Charities § 34 (2006) (recognizing "the disposition of property for charitable purposes ... can be in the form of an absolute transfer subject to conditions."). Indeed, as WU points out, a contrary rule would make many charitable donations wholly impossible or ineffectual. In this case, the signed consent forms and the brochure delineate the specific and limited recourse placed upon each RP's donation of biological materials should an RP change his mind about participating in the medical research: namely, the right to revoke voluntary participation in or consent to the research study, and, in some of the consent forms, the right to request destruction of the donated biological materials.

Under the terms of the consent forms and brochures, the RP's participation in genetic cancer research includes answering questions about the RP's family history of cancer, having blood drawn, and allowing excised tissue and blood samples to be sent to a laboratory and used for research at WU or other institutions. Additionally, should an RP experience a change of heart about participating in genetic cancer research, the RP is entitled to request his biological materials no longer be used, and under the terms of the brochures (and some of the consent forms as well), the materials would be identified and destroyed upon request. Viewing these provisions in their

entirety, it is evident the RPs did not retain the right to revoke and physically repossess the donated biological materials. Nor did the RPs retain the right to direct or authorize the use, transfer, or destination of the biological materials after their donation. The RPs' subsequent rights to their biological materials were expressly limited to the option to discontinue participation in the study to avoid answering additional questions, donating more biological materials, or allowing their biological materials to be used for further research. Beyond these particular and limited rights, the RPs retained no greater interest with regard to their biological materials. Such rights cannot be equated with or interpreted to include the broad privileges or proprietary interests advocated by the defendants.[7]

Dr. Catalona's past conduct, as well as the practical consequences of the research process itself, also refutes the defendants' position. While at WU, Dr. Catalona signed numerous MTAs and research agreements acknowledging WU's ownership of the biological materials. Moreover, during Dr. Catalona's tenure, he routinely ordered the destruction or "purging" of Biorepository samples in order to create more storage space, and did so without obtaining any additional consent from RPs. Dr. Catalona's habitual destruction of samples, in a manner consistent with

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[7] Because the specific language contained in the consent forms and brochures, as well as the circumstances surrounding the RPs' voluntary decision to donate their biological materials, convinces us the RPs intended to make inter vivos gifts of their materials, we find it unnecessary to address the effect or validity of the consent forms' waiver language ("By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate.")

apparent indifference to any proprietary interest of the donors, is at odds with his later assertion the RPs own the biological materials.[8] Furthermore, during research involving the use of prostate tissue and blood samples, the research process might consume an entire particular biological specimen, leaving behind no tangible material in which a donor could assert a potential proprietary interest. It is difficult to reconcile the use, consumption, and destruction of biological materials by Dr. Catalona and the events that occurred during the research process with the assertion the RPs retained an ownership interest in the donated materials.

Noticeably absent from the record is any mention the RPs ever were informed they could physically withdraw or request the return of their biological samples. Indeed, in no event could the samples physically be returned to their donors. Federal and state regulations prohibit such a result by defining excised body tissue and blood as hazardous substances or infectious waste, and by articulating the proper disposal method. See 29 C.F.R. § 1910.1030; Mo. Rev. Stat. §§ 260.200.1(17)5 260.203. Nor could RPs who were surgical patients reasonably have anticipated they had any right to have excised materials returned to them following surgery, because before undergoing surgical procedures, patients were required to sign standard surgical

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[8] Dr. Catalona's privileges to and treatment of biological samples while at WU comports with the terms of WU's Intellectual Property Policy, which provides "all intellectual property (including . . . tangible research property) *shall be owned by the University* if significant University resources were used or if it is created pursuant to a research project funded through corporate, federal or other external sponsors administered by the University." (emphasis added)

consent forms acknowledging that tissues removed during surgery and not used for clinical purposes would be destroyed as hazardous medical waste. Also absent from the record is any indication the RPs ever were informed they had the ability to direct the transfer of their samples to another entity for research purposes. Based on the record before us, we conclude WU's acceptance of the donated biological materials was absolute.

Thus, the district court properly concluded the RPs made informed and voluntary decisions to participate in genetic cancer research, and thereby donated their biological materials to WU as valid *inter vivos* gifts.[9] This voluntary transfer of tissue and blood samples to WU-without any consideration or compensation as an incentive for doing so-demonstrates WU owns the biological samples currently housed in the Biorepository. Whatever rights or interests the RPs retained following their donation of biological materials, the right to direct or authorize the transfer of their biological materials from WU to another entity was not one of them. Thus, the release forms authored by Dr. Catalona and signed by approximately 6,000 RPs are ineffective to transfer possession of biological samples housed in the Biorepository to another entity. Given WV's ownership of the biological materials, the district court neither abused its discretion in denying Dr. Catalona's motion for injunctive relief, nor erred in granting summary judgment in WV's favor.

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[9] Given our conclusion the RPs made *inter vivos* gifts to WU, it is unnecessary for us to address, in detail, whether the RPs are entitled to control the disposition of their biological materials under the law of implied bailments. However, in our view, the district court correctly rejected this argument as unavailing.

III. CONCLUSION

For the foregoing reasons, we affirm the well-reasoned opinion and judgment of the district court.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 06-2286

Washington University,
Appellee,

v.

William J. Catalona, M.D.,
Appellant.

Richard N. Ward, et al.,

Us Too International,
Amici on Behalf of Appellant

American Cancer Society; et al.,
Amici on Behalf of Appellee

No. 06-2301

Washington University;
Appellee

v.

William J. Catalona, M.D.,
Richard N. Ward, et al.,

Appellants

Us Too International and People's Medical Society,
Amici on Behalf of Appellant

American Cancer Society; et al.,
Amici on Behalf of Appellee

Appeal from U.S. District Court for the Eastern
District of Missouri – St. Louis
(4:03-cv-01065-SNL)

JUDGMENT

This appeal from the United States District Court was submitted on the record of the district court, briefs of the parties and was argued by counsel.

After consideration, it is herby ordered and adjudged that the judgment of the district court in this cause is affirmed in accordance with the opinion of this Court

June 20, 2007

Order Entered in Accordance with Opinion:
Clerk, US Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY,	)	
Plaintiff,	)	
VS.	)	Case No. 4:03CV106SNL
WILLIAM J. CATALONA, ET. AL.,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiff Washington University (hereinafter referred to as "WU") has filed this declaratory judgment action seeking to establish "ownership", and thereby, the destiny of certain research biological materials currently stored in the GU Biorepository. Central to the several pending summary judgment motions, and preliminary injunction motion(s) is the issue of "ownership"; thus, the Court determined that the most logical and efficient manner in which to address this issue was to hold a permanent injunction hearing in which all interested parties, including research participants who "donated" the subject biological materials, could coherently present their argument to the Court. On April 9 through 11, 2005, such a hearing took place before this Court. At the conclusion of the hearing, all parties were permitted to file post-hearing briefs, and this matter is now ripe

for disposition.

After careful consideration of all objections to exhibits and testimony taken with the case, all said objections are hereby overruled, and all exhibits offered into evidence at the hearing are received into evidence. All testimony will be considered by the Court and given its due weight. This Court, having now considered the pleadings, the testimony of witnesses, documents in evidence, and any other evidentiary materials submitted for the Court's consideration, and being fully advised in the premises, hereby makes the following findings of fact and conclusions of law as required by Rule 52, Federal Rules of Civil Procedure.

FINDINGS OF FACT[1]

Plaintiff Washington University (WU) is a Missouri not-for-profit corporation with its principal place of business in St. Louis, Missouri. WU is one of the leading private research universities in this country, if not in the world. As a research university, it has a medical school (Washington University School of Medicine) that includes a Department of Surgery and a Division of Urologic Surgery. The medical faculty regularly pursues and publishes significant original medical research. Within the

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[1] The Court's factual findings are derived from the transcripts of the permanent injunction hearing (Vols. 1-3); the parties' exhibits, deposition testimony, and the parties' briefs. Where necessary, the Court will cite to specific evidence and/or testimony. Where more than one copy of the same exhibit has been filed by different parties, the Court will cite to only one exhibit; however, the reference should not be considered any indication of bias on the part of the Court. Referring to only one of duplicative (in some cases, triplicative) exhibits is simply a matter of judicial efficiency.

Division of Urologic Surgery, WU physicians treat patients, teach students and residents, and conduct medical research. Defendant William J. Catalona, M.D.[2] is a highly respected urologist and urologic surgeon, as well as a well-established medical researcher regarding prostate cancer. He was employed by WU from July 1, 1976 until February 23, 2003. Dr. Catalona was Chief of the Urology Division from 1984 to 1998. While at WU, Dr. Catalona performed thousands of surgeries, including prostate cancer surgeries. He was instrumental in establishing the GU[3] Biorepository for the collection and storage of biological research materials. In 2003, Dr. Catalona left his position with WU to take a similar position with Northwestern University in Chicago, Illinois and to continue his prostate cancer research.

The GU Biorepository houses biological specimens of prostate tissue, blood, and DNA samples for prostate cancer research. Patients of Dr. Catalona, as well as several other WU physicians, contributed biomaterials for prostate cancer research. As of the date of the hearing, there were more than 30,000 research participants enrolled in prostate cancer research studies; of these, 2500-3000 had been patients of Dr. Catalona. There are approximately 3500 prostate tissue samples in the GU Biorepository taken from patients of Dr. Catalona and other WU physicians within the Urologic Surgery Division. There are approximately 100,000 serum samples in the GU Biorepository; 75% of these contributions were made from research participants who were not patients of Dr. Catalona or any other WU physician.

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[2] Defendant Catalona is also a Counterclaim Plaintiff.

[3] genito-urinary

Approximately 4400 men contributed DNA samples to the GU Biorepository; again, some were patients of Dr. Catalona, while others were not. The GU Biorepository is not used for clinical care or follow-up care; it is strictly used for research purposes. At times, other research institutions have requested and received samples from the GU Biorepository for research projects outside of WU (or in partnership with WU). The transfer of such material is made pursuant to a Material Transfer Agreement (MTA). At least seven (7) of these MTAs personally signed by Dr. Catalona acknowledge WU as the owner of the biological samples at issue in this case. Plaintiff's Exhibits 7-10, 12-14.

At all relevant times, the GU Biorepository has been housed in one or more buildings owned by WU. At all relevant times, WU employees have administered the GU Biorepository. WU has provided the majority of funding necessary to operate and maintain the GU Biorepository. External funding for the GU Biorepository is in the form of public and private grants made to and administered by WU as the grantee. Dr. Catalona, as a WU employee and physician, has raised several million dollars in outside funding for the GU Biorepository. Other WU employees, most notably Dr. Gerald Andriole (Dr. Catalona's successor as Urology Division Chief), have raised substantial funds for the GU Biorepository.

WU's Intellectual Property Policy states that "all intellectual property (including . . . tangible research property) shall be owned by the University if significant University resources were used or if it is created pursuant to a research project funded through corporate, federal, or other external sponsors administered by the University." Plaintiff's Exhibit

17, § I.3(a). It further states, "[G]enerally, creators and research investigators will retain custody of tangible research property while at the University." Plaintiff's Exhibit 17, § I.3(a).

Defendants Richard Ward, Thomas McGurk, Luis Garcia, Antonio Castro, Phillip Wilard, Ivan Parsons, James Ellis, and Michael Missios[4] are/were patients of Dr. Catalona and participants in one or more research projects at WU in which Dr. Catalona was involved.[5]

During the relevant time-period, several prostate cancer studies have been undertaken by Dr. Catalona and other doctors in the Urology Division. Dr. Catalona, as well as other WU physicians, were named "Principal Investigators" on these studies. Dr. Catalona testified that the principal investigator "is in charge of conducting [a] research protocol." Tr. 1:46.[6] The testimony at the hearing established that regardless of who was listed as the "Principal Investigator", the research studies were a collaborative effort involving substantial work by many individuals, all of whom were/are employees of WU.

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[4] Ward, McGurk, and Ellis testified at the hearing.

[5] In order for simplicity and judicial efficiency, the persons who contributed samples to the GU Biorepository are collectively referred to as "research participants" and include the eight (8) men who have been allowed to intervene in this case and refer to themselves as "patient/defendants."

[6] When citing to hearing testimony, the Court will use the following notation: "Tr" stands for transcript; the number following TR stands for Vol. 1, 2, or 3; and the number after the colon is the page number. Thus, the referenced testimony can be found in Vol. 1 of the hearing transcript on page 46.

In order to carry out the subject prostate cancer research studies[7], surgical and nonsurgical research participants (hereinafter referred to as "RPs") were invited to participate in genetic cancer research. If they agreed to participate, they had to sign "informed consent" forms. Although the informed consent forms differed slightly due to variances in the protocol and the particulars of each Principal Investigator, generally they all contained the similar language. The informed consent forms typically bore the WU Medical Center logo. Plaintiff s Exhibits 27, 58, 59, 60, 61, and 98; Catalona Exhibit UUU; RP Exhibit 1. The informed consent forms state that the collection of samples is for medical research and not for patient care. They typically stated that the RP could not "claim ownership rights" to any medical or scientific product that results from research with the sample. They typically use the word "donate" to characterize the delivery of the sample (blood, tissue and/or DNA) from the RP to the WU physician or another WU medical technician. They typically state that by participating, the RP "make [s] a free and generous gift of your [blood, tissue and/or DNA] to research that may benefit others." Furthermore, the typical WU informed consent form states that "[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Some forms use the phrase "withdraw my consent and discontinue participation." None of the submitted WU informed consent forms address the issue of the RP withdrawing samples from the GU Biorepository or the RP requesting

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[7] Testimony and documents refer to the cancer research studies as "protocols", a term which the Court may use from time to time.

samples be sent to another institution.

Along with the informed consent forms, RPs are given a WU Genetic Research Brochure (to also sign) which generally addresses the issues of primary importance to the RP. Catalona Exhibit X. Under the section: **What if you change your mind?**, the brochure states the following: "To request that your tissue no longer be used for research, you should call the investigator listed on the consent form. Your tissue will be identified and destroyed upon request. Any research results already obtained cannot be destroyed or recalled." Nowhere in the brochure does it state anything about a RP withdrawing his/her sample or a RP requesting that his/her sample be transferred to another facility.

WU is a federally approved and regulated institution for the human-subject research involving the GU Biorepository. The Department of Health and Human Services (HHS) office known as the Office for Human Research Protection (OHRP) is responsible for the oversight of compliance by WU, and all other federally-funded institutions, engaging in human-subject research studies.[8] The OHRP requires that such institutions and facilities comply with the federal regulations set forth at 45 C.F.R. Part 46, a.k.a. "The Common Rule".[9] Among other things, the Common Rule requires every institution conducting and/or sponsoring human-subject research to create and maintain an institutional review board a.k.a. IRB. 45 C.F.R. 46.103. "A IRB shall review and have authority to approve, required modifications, in (to

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[8] Prior to 1999, this office was known as the Office for Protection from Research Risks (OPRR).

[9] See Attachment A - 45 C.F.R. Part 46, Subpart A.

secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. 46.109(a). "An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 46.116." 45 C.F.R. 46.109(b). The IRB relevant to the GU Diorepository is known as the Human Studies Committee a.k.a. HSC.

The federal regulations also require WU to provide written assurance to the OHRP of its compliance with the Common Rule. 45 C.F.R. 46.103(a). Such "assurance" should include "(1) a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself;" (2) the designation of one or more IRBs established in accordance with the requirements of this policy; (3) a list of IRB members; and (4) "[w]ritten procedures which the IRB will follow (I) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review

and approval except when necessary to eliminate apparent immediate hazards to the subject." 45 C.F.R. 46.103 (b)(1)-(4).

In compliance with the federal regulations, as stated before, WU has created and maintained an IRB known as the HSC. The HSC has created and maintained a written document entitled **Policies/Procedures for Protection of Human Research Subjects.** Catalona Exhibit 0. The HSC has also created and maintained a written document entitled **Washington University School of Medicine - Human Studies Committee - Standard Operating Procedures.** Catalona Exhibit P. Finally, the DHHS has approved the relevant Multiple Project Assurance submitted by WU. Catalona Exhibit 1.

The Common Rule also sets forth certain requirements for informed consent. 45 C.F.R. 46.116. Foremost, the Common Rule requires that:

> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the

> representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Among the basic elements to be included in an informed consent are:

> (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

45 C.F.R. 46.116(a)(8).

Additional elements of informed consent, when appropriate, may include:

> (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject ...

45 C.F.R. 46.116(b)(4).

The federal regulations do not elaborate as to what is involved when a RP "discontinue[s] participation" and/or "withdraw[s] from the research". The federal regulations do not address the matter of a RP's "right" to physically possess their samples upon termination of their participation in a research study; or, a "right" to direct their sample[s] transfer to

another institution or Principal Investigator.

The OHRP publishes a guidance document addressing the issue of prohibited exculpatory language in informed consent forms. Catalona Exhibit Q. This document was the result of a 1996 Cooperative Oncology Chairperson Group meeting. The guidance document provides examples of "exculpatory language" that should not be considered for use in informed consent forms pursuant to 45 C.F.R. 46.116. One of the examples given states: "By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research." These examples are not listed anywhere or referred to anywhere in the relevant federal regulations.

Finally, 45 C.F.R. 46.117 requires that informed consent be documented as follows:

> (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form."
>
> (b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
>
> (1) A written consent document that embodies the elements of informed consent required by § 46.116. (remainder of paragraph omitted)

As of the date(s) of the hearing, no regulatory agency, including the OHRP, has taken any action against WU regarding the informed consent forms

used during the relevant time-period.

If a RP chooses to discontinue participation, federal and state regulations govern the options WU has regarding the tissue/blood/DNA sample. The undisputed testimony was that 1) WU may destroy samples it no longer needs for research; 2) store the samples indefinitely; and/or 3) choose to "anonymize" the samples and continue to use them in certain areas of research.[10] Furthermore, if a prostate cancer surgical patient elects not to participate in research at the time of his prostate surgery, that portion of the diseased tissue not needed for clinical use must, in accordance with federal and state regulations, be treated as hazardous medical waste and prohibit returning the excised tissue to the patient. 29 C.F.R. § 1910.1030 (bloodbome pathogens); §§ 260.200 R.S.Mo., 260.203 R.S.Mo. (infectious waste disposal); 10 C.S.R. § 80-7.101 (infectious waste management).

In early 2003, Dr. Catalona left WU for Northwestern University in Chicago, Illinois. He intended to continue his research in the area of prostate cancer. In connection with his anticipated departure and continuation of his research at Northwestern University; on or about February 18, 2003, he sent a letter to all research participants, whether or not they had been his patients, who had participated in his research protocols at WU. Catalona Exhibit HH. This letter informed these RPs of his departure from WU on or about February 24, 2003, of his continued availability for consultation and/or treatment, and his continuation for prostate

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[10] To "anonymize" a sample, all links to the RP's personal identifying data is removed and the sample is no longer "linked" to a particular RP.

cancer research. The letter was also included in a newsletter known as **"Quest"**, published quarterly by the Urological Research Foundation, of which Dr. Catalona was the Medical Director. Dr. Catalona testified that he believed that approximately 60,000 people received his February 18th letter either directly or via the Quest newsletter. Tr.2:32-33.

In apprising the recipients of the letter of his intention to continue his prostate cancer research, Dr. Catalona stated "[T]o succeed in these goals, I need to have the tissue and blood samples that patients, their relatives, and other research volunteers have contributed to me over the years. You have entrusted me with samples, and I have used them for collaborative research that will help in your future medical care and in the care of others for years to come." Attached to the February 18th letter was a "Medical Consent& Authorization" form stating:

> I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects.

The letter asks the recipient of the letter to sign this "authorization for release" form and return it promptly to Dr. Catalona. Catalona Exhibit HH. Approximately 6,000 recipients signed the form and returned it to Dr. Catalona. Tr.1:61; Tr.1:101; Catalona Exhibit JJJJ.

At the time that Dr. Catalona sent the February 18, 2003 letter and release form, he was still an

employee of WU. Furthermore, he was no longer the Principal Investigator on any of the research protocols involving the samples he sought to have transferred to Northwestern University. He had transferred the role of Principal Investigator on his remaining active research protocols to another WU faculty member/researcher, Dr. Brian K. Suarez. Plaintiff's Exhibit 29. The letter and release form was sent by Dr. Catalona without prior approval of any WU administrators or the approval of the HSC. At the time he sent the letter and release form, Dr. Catalona did not have any approved research protocol at Northwestern University nor had he obtained the approval of the Northwestern University IRB prior to sending the letter and release form.

In 2002 WU formed a Peer Review Panel to consider requests from researchers, both within WU and outside of WU, to obtain and use biological samples from the GU Biorepository. Prior to leaving WU, Dr. Catalona had submitted three (3) such requests, and all three (3) have been approved and the requested biological materials provided to him for his research. As of the date of the hearing, Dr. Catalona had not made any additional requests for biological materials from the GU Biorepository to the Peer Review Panel for consideration.

Conclusions of Law

As stated previously, the sole issue determinative of this permanent injunction; in fact of this lawsuit; is the issue of ownership. That is, once having made voluntary donations of biological materials for medical research to a research institution, do the research participants retain ownership rights in such materials in that they can direct said materials' use

and transfer to third-parties. WU argues that the RPs made voluntary donations; i.e. gifts, of biological materials and once these "gifts" were delivered to WU, WU became the sole owner with controls to use and storage (pursuant to applicable federal and state regulations). Dr. Catalona and the RPs argue that the RPs had donated their biological materials with the "intent" that such materials stay with Dr. Catalona for his research.[11] The RPs believe that they have retained ownership rights in their donated biological materials and can withdraw said materials and have them transferred to Dr. Catalona and/or Northwestern University via their discontinuation of participation in any research at WU and their signing of Dr. Catalona's consent form.

Missouri law governs the substantive issues of ownership and "gift/donation." It is well-settled that exclusive possession and control of personal property is *prima facie* evidence of ownership, and anyone else claiming such property bears the burden of proof. Foltz v. Pipes, 800 S.W.2d. 14, 15 (Mo.App. 1990); State v. Patchen, 652 S.W.2d. 265, 267 (Mo.App. 1983). The burden by the non-possessor asserting an ownership interest is met only by a preponderance of the evidence. Foltz, at 15; Patchen, at 267.

It is undisputed that at all times WU has been in exclusive possession of the subject biological materials. WU has supplied all facilities housing the GU Biorepository. WU personnel has consistently maintained and administered the GU Biorepository. Although some funding of the GU Biorepository has

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[11] It is undisputed by all the parties, and previously held by this Court, that Dr. Catalona has abandoned any legal argument as to his personal ownership of the subject biological materials.

been provided through Dr. Catalona's efforts, it was done so via his position at WU. The majority of funding for the GU Biorepository has been through the financial reserves of the Urology Division of the WU Medical School. It is undisputed that Dr. Catalona had access to the subject materials, but so did other researchers, both inside and outside of WU. Furthermore, such access was only through the IRB and HSC of WU. There was no evidence provided to this Court that any RP had access to his or her biological materials once such materials were made a part of the GU Biorepository.

WU had exclusive control over the subject biomaterials. As stated before, WU is solely responsible for deciding who can have access to the GU Repository and the use for such biomaterials. Even as Chief of the Urology Division, any decisions made by Dr. Catalona were made as a WU employee. WU alone bears all legal, regulatory, and compliance risks with respect to all research done in connection with the GU Biorepository. WU is a federally approved and regulated institution for the carrying out of human-subject research, for which the Biorepository was established. As such, it is continually responsible for ensuring that the GU Biorepository meets all necessary requirements; and does this through audits and substantial internal compliance programs. Due to the nature of the GU Biorepository, WU is subject to federal and state laws and regulations governing the disposal and storage of human biological matter, and it alone is responsible for compliance with such laws and regulations. There was no evidence presented to this Court that any RP is equally responsible for the control of the use of these materials in human-subject

research.

WU has continually asserted its ownership interests in the materials stored in the GU Biorepository. Its Intellectual Property Policy[12], in existence prior to this dispute arising, states that tangible research property, including biological materials, belong to WU if significant university resources were used or such property was obtained pursuant to a research project funded by an external sponsor administered by WU. Furthermore, in all MTAs concerning these materials, including those wherein Dr. Catalona was the "Provider's Scientist", WU clearly exerted its ownership interest without objection by Dr. Catalona.[13] Even in the instance wherein Dr. Catalona attempted to change the language of a MTA to reflect "co-ownership" with WU, and WU refused to modify the language in the MTA, Dr. Catalona still signed.[14]

There is little dispute as to the scarcity of legal precedent to assist the Court in addressing the situation that presently stands before the Court. The two (2) cases which provide the most guidance concluded that research participants retain no ownership of biological materials they contribute for medical research.[15] Greenberg v. Miami Children's

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[12] Plaintiff's Exhibit 17.

[13] Eg. Plaintiff's Exhibit 14 - MTA dated June 1, 2001 between WU and the University of Cincinnati.

[14] Albeit Dr. Catalona testified that he felt he had no choice but to sign; yet still felt he had proprietary interest in the subject biological materials, the Court finds that the document speaks for itself.

[15] Dr. Catalona and the patients/defendants have cited several other cases which the Court has reviewed and finds

Hospital Research Institute, Inc., 264 F. Supp. 1064 (S.D.Fla. 2003); Moore v. The Regents of the University of California, 51 Cal.3d. 120, 793 P.2d. 479, 271 Cal.Rptr. 146 (CA. 1990).

In Greenberg, *supra,* donors of human tissue and fluids (among others) sued the physician who received the biological materials, used them to isolate the gene causing Canavan disease, and then obtained patent and attempted to license the patent. The plaintiff donors claimed, among other things, that they had a property interest in their excised body tissue and in the genetic information extracted from such tissue; as well as the registry which contained the donors' personal and genetic information. They asserted that the defendant(s) had "converted" such information for the defendant(s)' own exclusive economic benefit. Id at 1074. The Court held that it "disagrees and declines to find a property interest for the body tissue and genetic information voluntarily given to Defendants. These were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples, and thus conversion does not lie as a cause of action." Id., at 1074.

After recognizing that a claim of conversion was first predicated upon an ownership interest, the Florida district court, in adopting the reasoning of the Moore case, found that the plaintiff donors had no cognizable property interest in body tissue and

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inapplicable. These cases involved sperm donation, possession of a dead body, and tax liability for donated blood, among other issues. None of the cases cited by Dr. Catalona and/or the patients/defendants involved the donation of biological materials for **medical research.**

genetic matter donated for medical research. Greenberg, at 1074. After reviewing Florida state court opinions regarding property rights and body tissue, as well as Florida statutes regarding genetic materials, the Florida district court found that "the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party." Id., at 1075. It refused to recognize a claim of conversion because the blood and body tissue were "voluntary donations to medical research" and were donated "without any contemporaneous expectations of return." Id., at 1075-76.

In Moore, *supra*, a patient undergoing treatment for hairy-cell leukemia had portions of his removed spleen, and samples of his blood, blood serum, skin, bone marrow aspirate and sperm utilized in medical research without his knowledge and/or consent. This research resulted in a cell line which was patented by the defendants. The defendants ultimately entered into commercial agreements for the commercial development of the cell line and the resulting products. The patient plaintiff brought suit alleging conversion and breach of physician's disclosure obligations. As for his conversion claim,

> [H]e theorizes that he continued to own his cells following their removal from his body, at least for the purpose of directing their use, and that he never consented to their use in potentially lucrative medical research. Thus, to complete Moore's argument, defendants' unauthorized use of his cells constitutes a conversion. As a result of the alleged conversion, Moore claims a proprietary interest in each of the products that any of the defendants might ever create from his cells or

the patented cell line.

Id., at 134-35.[16]

The California Supreme Court did an exhaustive review of the law relating to the ownership and use of human biological materials. Having noted that Moore could not reasonably expect to retain possession of his excised cells, his claim for conversion had to rest upon retaining an ownership interest in them; however, the Court could find no reported judicial decision which would support a finding that he retained such an interest. Id., at 136-37. Instead the Court found that the laws governing human tissues, blood, and other biological materials were better suited, than court cases dealing with the law of conversion, to deal with regulating their disposition. Id., at 137. "It is these specialized statutes, not the law of conversion, to which courts ordinarily should and do look for guidance on the disposition of human biological materials." Id., at 137. One of the things making Moore's ownership claim "problematic" for the California Supreme Court was California's statutory law which severely limits a patient's control over excised cells. Essentially, California's laws negate any ownership rights a patient may have to excised cells since such biological materials are considered to be potentially hazardous biological waste materials and have to be disposed by a method approved by the state to protect the public health and safety. Id., at 140. Ultimately, the California Supreme Court refused to bestow ownership rights to the patient/plaintiff for several reasons, including that it felt that even if a patient had "some limited

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[16] For judicial economy and clarity, the Court will short cite to the California 3rd Reporter.

right to control use of excised cells" such a "right" is already protected because, "a fully informed patient may always withhold consent to treatment by a physician whose research plans the patient does not approve." Id., at 141.

Both the Greenberg and the Moore cases found the research participant to be a "donor" who had parted with any semblance of ownership rights once their biological materials had been excised for medical research. Both courts reviewed relevant caselaw, addressed policy considerations, and addressed the implications of applicable federal and/or state laws dealing with biological materials. The Court finds their analysis to be persuasive, and in light of its own review of applicable Missouri law, finds that WU has met its burden in establishing ownership of the subject materials and that the RPs have not put forth adequate evidence to challenge WU's ownership claim.

Furthermore, the Court finds that the RPs are "donors" and the subject biological materials constitute an *inter vivos* gift. The elements of an *inter vivos* gift are: 1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3) acceptance by donee whose ownership takes effect immediately and absolutely. In re Herman Jerome True, 285 B.R. 405, 413-14 (Bankrpcy Ct., W.D.Mo. 2002); Wantuck v. United Savings and Loan Assn., 461 S.W.2d. 692, 694 (Mo. 1971); In the Estate of Marv F. Campbell, 939 S.W.2d. 558, 562 (Mo.App. 1997); Duvall v. Henke, 749 S.W.2d. 714, 716 (Mo.App. 1988). The person claiming that the gift exists has the burden of proving it with clear, cogent and convincing evidence. In re Herman Jerome True, at 414; In the Estate of Marv

F. Campbell, at 562; Duvall, at 716.

"Specific language is not required to reflect present intent to make a gift on the part of donor." Duvall, at 716. The circumstances surrounding the donation can create an inference that the donor had the present intent to make the *inter vivos* gift to the donee. Duvall, at 716. In fact, "[c]onduct can be an enlightening ingredient in discerning intent." In the Estate of Maa F. Campbell, at 562.

The RPs all signed informed consent forms that clearly stated that they were agreeing to participate in medical research studies at WU. Tr.2:10. Many of the RPs were patients of WU doctors other than Dr. Catalona. Tr. 1:83 Many of the RPs donated biological materials for research protocols having someone other than Dr. Catalona as the Principal Investigator. Plaintiff's Exhibits 56, 57, 58, 59; Tr.1:80-82; Tr.2:94-97. The informed consent forms typically bore the WU Medical Center logo. The informed consent forms stated that they were not valid without the stamp of approval of the WU Human Studies Committee. The forms advised the RPs that they could contact the Chairman of the WU Human Studies Committee with any concerns, The forms advised the participants what WU would do to protect their privacy and minimize the burdens of participating in the study.

Nowhere in the forms were RPs advised that they were entrusting their samples to Dr. Catalona only. In fact, in those research protocols wherein Dr. Catalona was the Principal Investigator, the forms merely stated: "You are invited to participate in a research study conducted by Dr. William J. Catalona and/or colleagues." Plaintiff's Exhibits 27, 61, 98; Catalona Exhibits UUU (McGurk and Ellis informed

consent forms); Patients' Exhibit 1 - Ward informed consent form.

The Court finds that the RPs had the present intent to make *inter vivos* gifts; *i.e.*, donations of their biological materials to WU for medical research.

Furthermore, the Court finds that for the reasons stated in establishing WU's ownership of the subject biological materials, WU took delivery of these materials and its acceptance of said materials immediately and absolutely effectuated WU's ownership of these materials.

Dr. Catalona and the RPs challenge WU's ownership rights by asserting the following grounds: 1) that no gift was made because of "exculpatory language" in the informed consent forms; 2) no gift was made to WU because the RPs "intended" for their samples to go with Dr. Catalona wherever he may go to conduct research; 3) that the RPs have retained their ownership rights to their excised biological materials because their "right to discontinue participation" includes a "right to control the samples' use" and a "right to transfer their samples" to a specific person or entity; 4) that the informed consents are invalid as being violative of certain ethical documents regarding human-subject research; and 5) the RPs made a bailment of their biological materials, not an *inter* vivos gift to WU. The Court has carefully reviewed each of these arguments and finds them meritless.

As stated before, an *inter vivos* gift only requires donative intent, delivery, and acceptance. There is no requirement that the gift be made pursuant to any written document. See Ridenour v. Duncan, 246 S.W.2d. 765, 769 (Mo. 1952) ("Language,

written or spoken, expressing an intention to give does not constitute a gift unless the intention is executed by a complete and unconditional delivery of the subject matter or a delivery of a proper written instrument evidencing the gift."); In re Estate of Gladys Piper, 676 S.W.2d. 897, 899 (Mo.App. 1984)(*citing* Ridenour, *supra*). Since delivery of the subject biological materials was made and accepted by WU, the existence of the informed consent forms in [sic] inconsequential.

However, because of the nature of the gift, federal regulations require some form of informed consent. Dr. Catalona and the RPs argue that the presence of "exculpatory language" invalidates the informed consents and therefore, negates the gifts. In support of this argument, they point to the OPRR guidance document (Defendant's Exhibit Q). As this Court has already determined, this document is not legally-binding upon WU. It merely presents an opinion by the OPRR regarding exculpatory language in informed consent forms and provides examples. These examples are not found in any of the federal regulations governing the GU Biorepository.

The governing federal regulation (as to informed consent), 45 C.F.R. § 46.116, only prohibits exculpatory language in the form of a waiver or release from liability.

> No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears to release the investigation, the sponsor, the institution or its agents from liability for negligence.

It is clear that the only legal obligation WU had was not to include exculpatory language in its informed consent forms which waived any legal rights the RP may have or relieve any party from liability for negligence. Hearing testimony from all experts indicated that the research community consistently understood 45 C.F.R. § 46.116 to bar exculpatory language involving releases from malpractice or other negligence. The OPRR's opinion as to exculpatory language does not govern the informed consents and therefore, does not affect the ownership interest of WU in the materials stored in the GU Biorepository.

Next, Dr. Catalona and the RPs argue that the RPs never intended for WU to have ownership rights to the donated biological materials; i.e. that their intent was to retain such rights and continue to exercise their ownership rights as to the use and location of their excised biological materials.

As stated earlier, one of the elements of a gift is present donative intent. Present donative intent is assessed by determining if a gift was intended at the time of the initial transaction. Michaelson v. Wolf, 261 S.W.2d. 918, 925 (Mo. 1953). A completed *inter vivos* gift cannot be revoked by the donor once the gift is delivered and accepted by the donee. Clippard v. Pfefferkorn, 168 S.W.3d. 616, 619 (Mo.App. 2005); Donnelly v. Donnelly, 951 S.W.2d. 650, 653 (Mo.App. 1997). "An afterthought of regret does not nullify the passage of title by a delivery and made by the grantor." LeMehaute v. LeMehaute, 585 S.W.2d. 276, 281 (Mo. App. 1979).

The Court finds that the RPs had the present intent to donate their biological materials to WU to be maintained in the GU Repository. The informed

consent forms repeatedly asserted WU's ownership of the donated materials and only listed Dr. Catalona as the Principal Investigator. Although the Court respects the testimony given by Messrs. Ward, Ellis, and McGurk, it was clear that these gentlemen all had a deep personal connection to Dr. Catalona, and believed that they owed their lives to him. The Court understands and appreciates these feelings but their testimony regarding intent, especially now after getting Dr. Catalona's letter, is suspect or at least, shows nothing more than an "afterthought of regret". There was no testimony by any of these gentlemen that they did not read nor understand the informed consent forms prior to signing. The forms spoke of "donation" and at least two (2) forms (Ward and McGurk) referenced a waiver of any claim to the excised body tissues. Since Ward, Ellis, and McGurk were presumably testifying on behalf of the eight (8) patients who joined the case, and reflect the opinion of all RPs who signed Dr. Catalona's "consent to transfer" form, the Court finds that all RPs who donated biological materials to the GU Repository, whether or not patients of Dr. Catalona, donated such materials with the present intent of making an *inter vivos* gift to WU.

Next, Dr. Catalona and the RPs argue that the RPs right to discontinue participation includes the right to continue control over the use and location of their excised biological materials. There is nothing stated in the governing federal regulations which equates a right to discontinue participation with a right to control the disposition and use of the excised biological materials. The relevant testimony at the hearing indicated that only three (3) things happen when a RP chooses to "discontinue participation": 1)

WU may destroy the sample; 2) WU may store the sample indefinitely without any further use; or 3) WU may remove all identifying markers and use the sample in exempt "anonymized" research. Dr. Goodman and Dr. Clayton both agreed that research samples can be destroyed even without approval of the RP; and in fact, Dr. Catalona has done this on several occasions. No one questioned WU's ability to simply store the samples indefinitely after a RP discontinues participation in a research project. Finally, Drs. Ludbrook and Prentice both testified that anonymization is a response available to WU when a RP chooses to discontinue participation in research.[17]

The Court finds that the right to discontinue participation in a research project means nothing more that the RP has chosen not to provide any more biological materials pursuant to one or more research protocols; i.e., not to make any more *inter vivos* gifts of donated biological materials to WU. Nothing more can or should be read into this right possessed by the RPs at all times.

Next, Dr. Catalona and the RPs argue that WU's refusal to transfer the donated biological materials violates the Belmont Report, the Declaration of Helsinki, and the Nuremberg Code. The Belmont

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[17] "Although not particularly relevant to the matter at hand, the Court does note that even Dr. Catalona, as a researcher at Northwestern University, testified that he is using informed consent forms which only state two (2) options upon a RP's decision to withdraw participation: 1) destruction of the sample or 2) anonymization of the sample. Northwestern University's consent form interestingly does not provide the third option advocated by Dr. Catalona and the RPs; i.e. return of the sample to the RP or transfer of the sample to a location chosen by the RP.

Report is the 1979 report of a Presidential Commission that summarizes the basic ethical principles underlying the conduct of biomedical and behavioral human subject research. Defendant's Exhibit MMMM. The Declaration of Helsinki is a statement of ethical principles to provide guidance to physicians in connection with human subject research. Defendant's Exhibit NNNN. The Nuremberg Code, developed as a result of the war criminal trials before the Nuremberg Military Tribunals following World War II, and in response to the human experimentation experiments of Nazi Germany, similarly deals with ethical principles governing human subject research. Defendant's Exhibit OOOO. All of these documents set forth international ethical principles relating to human subject research.

Although WU does have an agreement with DHHS to be guided by the ethical principles in the Belmont Report[18], said agreement fails to provide a basis for the claims of Dr. Catalona and/or the RPs wishing to transfer their samples (including the eight patients who are parties to this lawsuit) because they are not parties to or the third-party beneficiaries of this government contract. They have no private cause of action to enforce the terms of the contract. See Wright v. Fred Hutchinson Cancer Research Center, 269 F.Supp.2d. 1286, 1290 (W.D. Wash. 2002). Furthermore, the Court finds that Dr. Catalona and the RPs have failed to make an adequate showing that the refusal of WU to transfer the subject samples constitutes a violation of the DHHS Assurance Contract; and therefore, a violation of

[18] "Defendant's Exhibit I

the Belmont Report.

There is no private right of action for an alleged violation of international law for the protection of human research subjects based upon the Declaration of Helsinki and the Nuremberg Code. White v. Paulsen, 997 F.Supp. 1380, 1383 (E.D.Wash. 1998); Hoover v. West Virginia Dept. of Health and Human Services, 984 F.Supp. 978, 980 (S.D.W.Va. 1997) *aff'd* 129 F.3d. 1259 (4th Cir. 1997); see also Abdullahi v. Pfizer, Inc., 2005 WL 1870811 (S.D.N.Y. 2005).[19] Furthermore, this Court agrees with the conclusions reached by its fellow district courts in Michigan and Oklahoma that the standard in the United States for conducting research on human subjects is contained in the Code of Federal Regulations and therefore United States federal courts have no need to resort to international law to impute a standard. Ammend v. Biopart, Inc., 322 F.Supp.2d. 848, 872-73 (W.D.Wash. 2004); Robertson v. McGee, 2002 WL 535045 (N.D. Okla 2002).

Finally, Dr. Catalona and the RPs assert that the RPs did not make a "gift" of the subject biological materials but instead made a "bailment" and that WU stands only in the position as a bailee.[20] This argument fails for the simple reason that when a

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[19] Although it is not this Court's common practice to cite to unpublished opinions, it will do so in the rare instance wherein such opinion offers guidance helpful to this Court on a particular issue.

[20] Actually, Dr. Catalona and the RPs assert an "implied bailment". "A contract for bailment may be written, oral, express, or implied." D.S. Sifers Corp. v. Hallak, 46 S.W.3d. 11, 16 (Mo.App. 2001) *quoting* Stone v. Crown Diversified Indus. Corp., 9 S.W.3d. 659,669 (Mo.App. 1999).

"gift" is made, the giftor/donor has no expectation of getting the "gift" back; however, when a "bailment" is made, the bailor has every expectation of receiving back the subject of the bailment. A bailment is made on the condition that the property (after delivery by bailor and acceptance by bailee) be restored to the bailor according to his/her directions as soon as the purpose for the bailment ceases. Seitz v. Leman Bank & Trust Co., 959 S.W.2d. 458, 461 (Mo. 1998); Stone v. Crown Diversified Indus. Corp., at 669. There was no evidence presented to this Court that any of the RPs, including the three (e) RPs that testified, had ever informed NW, at the time of "delivery" of the subject biological materials that they wanted the samples returned to them. Furthermore, the RPs could not have had a reasonable expectation of restoration of the subject biological materials to them because applicable federal and state regulations governing the disposal of medical waste prohibit the return of such biological materials to the RPs. See 29 C.F.R. § 1910.1030; §§ 260.200, 260.203 R.S.Mo.; 10 C.S.R. § 80-7.010.

Finally, the medical research community itself has never considered the relationship between an RP and a medical research institution to be one of bailment. All the experts testified that they knew of no instance wherein a research participant had his/her samples returned to them. Even Dr. Catalona testified that he could only recall one or two instances wherein a biological sample had been returned to a patient, for clinical purposes.[21] The Court finds that no implied

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[21] Dr. Catalona's testimony was that out of approximately 40,000 research participants he had one or two who requested their samples back and the samples were processed and actually sent to a clinical laboratory (of the RP's choosing), not the RP's home.

bailment existed, at any time, in connection with any RP, as to the samples stored in the GU Repository between an RP and WU.

In connection with their argument that the RPs "own" their excised biological materials and can transfer them to any institution or person of their choosing, Dr. Catalona advances the notion that his letter and "Medical Consent and Authorization" form allegedly signed by approximately 6000 RPs effectively legally carries out the RPs' "right to discontinue participation". However, one views this document(s), it in no way provides a legal vehicle by which any RP can "discontinue participation" in any research protocol at WU.

Every expert and even Dr. Catalona testified that the letter/form did not constitute "informed consent" pursuant to the applicable federal regulations. It was never submitted to any IRB, either at WU or Northwestern University, for prior approval. Contrary to Dr. Catalona's opinion, the Court finds that his communication to the RPs was a "change" to his research protocols. He was no longer the Principal Investigator on any of the studies involving the samples he sought to have transferred; he was no longer an employee of WU nor continuing to conduct his research at WU, and Northwestern University (at that time) had not approved any "new" research protocols for him which would involve use of the biological materials he wanted transferred. Furthermore, the context in which this form was sent is troubling to the Court. He sent it to RPs, many of whom were his patients and emotionally tied to him, advising them of his move, of his desire to continue

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Tr.2:16-17

his consultation/treatment practice, and then describing his need to use these samples to further his help to them. Such a communication smacks of undue influence. Quite simply, the letter and form did not act in any legal authoritative manner to effectuate a transfer of the subject biological materials as part of a RP's right to discontinue participation.

As a final note, the Court wishes to address the possible (if not, probable) public policy ramifications of Dr. Catalona and the RP's position. The amicus brief filed by the Association of American Medical Colleges[22] succinctly mirrors the Court's concerns. Currently, these materials are housed and maintained by institutions federally and state regulated. A "check and balance" system is in place to monitor the research being conducted using these materials. The safety and welfare of human subject participants is protected through a variety of legal and professional standards administered by committees of persons schooled in the fields most privy to the needs of the medical/science community. Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a RP, these highly-prized biological materials would become nothing more than chattel going to the highest bidder. It would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most. Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. The integrity and utility of all biorepositories

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[22] Document #106, filed April 6, 2006

would be seriously threatened if RPs could move their samples from institution to institution any time they wanted. No longer could research protocols rely on aggregate collections since individual samples would come and go. Accountability would no longer exist since institutions would merely be warehouses filling purchase orders.

More alarming is the great potential for prejudicial influences into medical research. Allowing an RP to choose who can have the sample, where the sample will be stored, and/or how the sample can be used is tantamount to a blood donor being able to dictate that his/her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man. This kind of "selectiveness" is repugnant to any ethical code which promotes medical research to help all of mankind.

Accordingly, the Court finds that 1) defendants; i.e. Dr. William Catalona and the eight (8) research participants who are parties to this action, have failed to demonstrate that they are entitled to any injunctive relief; 2) that plaintiff Washington University owns all biological materials, including but not limited to blood, tissue, and DNA samples, in the GU Repository; 3) that neither Dr. William Catalona nor any research participant in connection with any research protocol conducted under the auspices of Washington University has any ownership or proprietary interest in the biological samples housed in the GU Repository; and 4) that the "Medical Consent & Authorization" forms authored by Dr. William Catalona and either directly or indirectly delivered to any research participant and signed by any research participant are void and

ineffective to transfer ownership and/or possession of any biological samples housed in the GU Repository to Dr. William Catalona, Northwestern University, any other research facility/institution, or any or all research participants.[23]

Dated this 31st day of March, 2006.

/s/ Stephen N. Limbaugh

Senior United States District Judge

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[23] Nothing in this opinion or the Court's ultimate findings shall be construed to prohibit Dr. William Catalona from seeking said samples through the ordinary and regular channels normally available to any medical researcher requesting approval of a research protocol from WU

APPENDIX D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY,	)	
	)	
Plaintiff,	)	
	)	
VS.	)	**Case No. 4:03CV1065SNL**
	)	
WILLIAM J. CATALONA, ET. AL.,	)	
	)	
Defendants.	)	

ORDER

In accordance with the memorandum opinion filed herein this date,

IT IS HEREBY ORDERED that plaintiff Washington University's motion for summary judgment (#24), filed January 7, 2004 be and is **GRANTED.** Judgment is hereby entered in favor of Washington University and against defendant William J. Catalona and the Intervener-Defendants Richard N. Ward, Thomas A. McGurk, Jr., Luis Garcia, Antonio Castro, Phillip Wilard, Ivan Parron, James D. Ellis, and Mike Missios on the merits of plaintiff Washington University's declaratory judgment complaint.

IT IS FURTHER ORDERED that defendant Catalona's motion requesting court order that plaintiff not utilize, disseminate, transfer, dissipate, de-identify and/or destroy serum and genetic

material at issue (#39), filed June 8, 2004 be and is **DENIED.**

IT IS FURTHER ORDERED that defendant Catalona's counterclaim be and is **DENIED.**

IT IS FURTHER ORDERED that this Court declares plaintiff Washington University the true and rightful owner and possessor of all biological materials, including but not limited to blood, tissue, and DNA samples, currently and in the future, stored and maintained in the GU Biorepository; and that neither Dr. William Catalona nor any research participant in connection with any past, present, or future protocol conducted under the auspices of Washington University has any ownership or proprietary interest in the said biological materials housed in the GU Biorepository. Washington University is free to use said biological materials for appropriate research projects and to transfer such materials to qualified researchers at other institutions pursuant to Material Transfer Agreements recognizing Washington University's ownership of the said materials. Any person or entity interfering with Washington University's ownership and/or possessory rights pertaining to said materials, or with Washington University's relationship with the NCI researchers or any other qualified researchers seeking access to the GU Biorepository materials, may be held in contempt of this order.

IT IS FINALLY ORDERED that nothing in this order and/or memorandum opinion, filed herein this date, shall be construed to prohibit Dr. William Catalona, from seeking access to the said biological materials stored in the GU Biorepository through the ordinary and regular administrative channels

normally available to any medical researcher requesting approval of a research protocol and/or use of said materials in an approved research protocol outside of Washington University.

Dated this 31st day of March, 2006.

/s/ Stephen N. Limbaugh

Senior United States District Judge

APPENDIX E

TITLE 45—PUBLIC WELFARE

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46 PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart A. Basic HHS Policy for Protection of Human Research Subjects

Sec. 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in

or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260) [56 FR 28012, 28022, June 18, 1991, as amend. at 70 FR 36328, June 23, 2005]